

the first paragraph of page 2 of the specification as follows:

~~In 1987, the~~The composition was sold under the name of "Collagen Beauty ProteinTM" (Smarter Nails & Hair, Inc., Newport Beach, CA). ~~In 1987, "Collagen Beauty Protein TabletsTM" (Smarter Nails & Hair, Inc., Newport Beach, CA) was sold~~compressed into 1,000 mg. tablets which comprised collagen powder and 10 mg. Vitamin C ~~compressed into 1,000 mg. Tablets.~~

IN THE CLAIMS

Rejection of Claims Pursuant to 35 U.S.C. § 112

Present Claims 10, 12-14 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failure to particularly point out and distinctly claim the subject matter which Applicant regards as his invention.

Present Claim 10 was rejected as indefinite for use of the word "ground" was not defined in that it does not set forth the meets and bounds of obtaining a "ground" cartilage composition. In response, Applicant asserts that the word "ground" is not indefinite. The specification sets forth that the frozen cartilage is "ground into mesh" prior to milling the dried cartilage into "a fine mesh" powder. See last paragraph of page 3 and lines 1-6 of page 5 and original Claim 15. There is no suggestion that an alternative definition, such as an "electrical ground" could be applied. Applicant asserts that a person of ordinary skill in the art, after reading the specification, would interpret the word "ground" therein as not indefinite since "ground" is used in the specification as a past tense for the state of the frozen cartilage material after it was subjected to the grinding step. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Present Claims 12-14 were rejected as indefinite for lack of use of the degree symbol between "95" and "C." Please amend present Claims 12 and 14 as follows:

Claim 12 (currently amended): The method of claim 10 wherein the sterilizing ~~of the ground cartilage is accomplished by step~~ includes heating the ground cartilage at a minimum of 95 C to at least 95°C for a minimum of at least 30 minutes.

Claim 14 (currently amended): The method of claim 10, wherein the drying ~~of the ground cartilage is accomplished by step~~ includes heating the ground cartilage at a minimum of 95 C to at least 95°C for a minimum of at least 6 hours.

Applicant was unable to identify a temperature set forth in present Claim 13.

Present Claim 13, however, was further rejected as indefinite for lack of citation to any active, positive steps in delimiting how use of ethanol is actually practiced. Applicant requests that present Claim 13 be amended as follows:

Claim 13 (currently amended): The method of Claim 10 wherein the defatting step includes treating of the ground cartilage is accomplished by using with ethanol.

Accordingly, Applicant requests that, as amended and traversed, the rejections for indefiniteness under 35 U.S.C. § 112, second paragraph, have been overcome.

Rejection of Claims Pursuant to 35 U.S.C. § 102

Present Claims 10-12 and 14-15 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,025,327 to Alkayali. In response, Applicant respectfully asserts that said claims are not anticipated by Alkayali or any other prior art.

In the instant Office Action, the Examiner cited Alkayali, issued on February 15, 2000, as the sole basis for the anticipation rejection. To bar claims under 35 U.S.C. § 102(b), requires the reference to have been patented "more than one year prior to the date of application" As an initial matter, even if Applicant were to accept that the rejected claims were disclosed in Alkayali, the rejection is not proper because the subject application was filed on January 24, 2001, less than one year after Alkayali had issued. The rejection should thus be withdrawn.

As an additional ground to overcome the rejection, Alkayali does not teach each and every limitation set forth in present Claim 10. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). The present Claims 11-15 depend from present Claim 10. Thus, Alkayali must contain each and every limitation of Claim 10 in order to be a proper basis under 35 U.S.C. § 102(b) for rejection of Claim 10 and claims depending therefrom.

Alkayali, however, fails to teach or disclose a method of preparing collagen type II powder that includes the grinding step recited in present Claim 10. Alkayali also fails to teach or disclose the two filtering steps, the defatting step, and the milling step of present Claim 10. Accordingly, present Claims 10-12 and 14-15 are not anticipated by Alkayali. Furthermore, Alkayali does not render any of these claims obvious.

Moreover, and contrary to the Examiner's assertion, there is nothing in the disclosure of Alkayali that expressly or inherently teaches or suggests that a sufficient, or even any, defatting effect occurs as a consequence of the addition of proteolytic enzyme to cartilage to form a hydrolysate.

Furthermore, as related to present Claim 14, the Examiner concedes as part of his second § 103 rejection, *infra*, that "Alkayali does not teach drying, a composition comprising collagen, by heating the composition at a minimum of 95°C for a minimum of 6 hours." See OA, pg. 10, 2nd para., 3rd sent. Accordingly, present Claim 14 cannot be anticipated by Alkayali. Furthermore, Alkayali does not render present Claim 14 obvious. For all the reasons set forth above, Applicant hereby respectfully requests that the instant rejection be withdrawn.

Rejection of Claims Pursuant to 35 U.S.C. § 103

Rejection of Present Claims 10 and 13 under 35 U.S.C. § 103(a) in view of Alkayali and O'Leary

In the first of two rejections under 35 U.S.C. § 103(a), present Claims 10 and 13 were rejected as being unpatentable over U.S. Patent No. 6,025,327 to Alkayali in view of U.S. Patent No. 5,073,373 to O'Leary. Alkayali discloses a method to prepare a collagen II hydrolysate, including at

least one natural protease, and prepared from bird articular cartilage, for use as an oral nutritional supplement. O'Leary discloses a "flowable demineralized bone powder composition" for use in the surgical repair of bone defects. O'Leary, Col.1, lns. 27-29. Components comprising the O'Leary composition include bone powder, a carrier or suspension agent, and one or more of a large number of optional substances such as, for example, antiviral drugs, antibiotics, antitumor agents, bone digesters, cellular attractants, and attachment agents. O'Leary, Col. 3, lns. 16-22 and Col. 4, 17-23.

To establish *prima facie* obviousness, all the claim limitations must be taught or suggested in the referenced prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). As discussed in the response to the 35 U.S.C. § 102(b) rejection above, Alkayali fails to teach or disclose the two filtering steps, the defatting step, and the milling step recited in present Claim 10. Similarly, O'Leary fails to teach or disclose the two filtering steps, defatting of ground cartilage, and the milling step of present Claim 10. Thus, the two references as combined do not teach, disclose or suggest all of the limitations of present Claim 10. Accordingly, present Claim 10 by definition is non-obvious. Additionally, any claim depending from a non-obvious claim is also non-obvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). As a result, present Claim 13 is also non-obvious. This result is not changed notwithstanding any potential suggestion in the prior art that ethanol is well known as a defatting agent. Accordingly, the rejection should be withdrawn.

To establish *prima facie* obviousness also requires some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. As a second ground to overcome the rejection, there is indeed no suggestion or motivation in the cited references to defat avian collagen in preparation of a nutritional supplement for oral administration. O'Leary discloses use of ethanol as part of a procedure to demineralize bone prior to formation of the surgical bone repair paste. See O'Leary, 2:14. There is simply no motivation suggested in the references that one of ordinary skill in the oral supplement art would turn to the surgical bone repair art for guidance. The arts are non-analogous. Moreover, the level of skill in the art can not be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Intl. Inc.*, 174 F.3d 1308 (Fed. Cir. 1999); *In re Kotzab*, 217 F.3d 1365, 1371 (Fed. Cir. 2000). Failure to establish some suggestion or motivation to combine the cited references must result, as here, in a finding of non-obviousness. Accordingly, the rejection should be withdrawn.

Rejection of Present Claims 10 and 14 under 35 U.S.C. § 103(a) in view of Alkayali and Reis

Pursuant to the Examiner's second rejection under 35 U.S.C. § 103(a), present Claims 10 and 14 were rejected as being unpatentable over U.S. Patent No. 6,025,327 to Alkayali in view of U.S. Patent No. 4,389,487 to Reis. Reis discloses subjecting a chemically-treated bovine tendon composition after freeze-drying to treatment with either heat or hydrogen halide gas. Reis discloses the advantages of such treatment after chemical treatment and freeze-drying is to increase "the absorption and the wet strength of the collagen product." Reis, Col. 2, lns.15-17.

As set forth above, to establish *prima facie* obviousness, all the claim limitations must be

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taught or suggested in the referenced prior art. *In re Royka*, 490 F.2d 981 (CCPA 1974). As discussed in the response to the 35 U.S.C. § 102(b) rejection above, Alkayali fails to teach or disclose the two filtering steps, the defatting step, and the milling step recited in present Claim 10. Similarly, Reis fails to teach or disclose the two filtering steps, defatting of ground cartilage, and the milling step of present Claim 10. Thus, Alkayali and Reis as combined do not teach, disclose or suggest all of the limitations of present Claim 10. Accordingly, present Claim 10 by definition is non-obvious. Additionally, any claim depending from a non-obvious claim is also non-obvious. *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). As a result, present Claim 14 is also non-obvious. Accordingly, the rejection should be withdrawn.

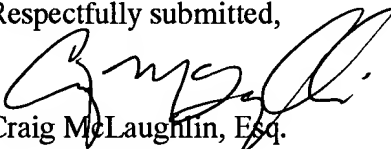
Additionally, the specification of the present invention discloses drying the ground collagen II composition in preparation for milling it into a fine mesh. See pg. 5, lns. 5-6 of the specification and original Claim 15. Reis disclosed advantages of heating a bovine tendon composition after it was treated with hydrochloric acid, sodium chloride, and acetic acid, and then freeze-dried. An advantage, as disclosed in Reis, of heating the composition after such treatment was to increase "the absorption and the wet strength of the collagen product." Reis, Col. 2, lns.15-17. As set forth above, however, there is no mention in Reis of avian sternal cartilage or collagen II or mention in Reis or Alkayali of a milling step or preparation therefore. Indeed, there is no motivation or suggestion in the references to show that one of ordinary skill in the oral supplement art would have looked to Reis for a procedure to dry the collagen II composition in preparation for milling it into a fine mesh. The rationale in Reis for heating the bovine composition does not suggest the heating step in present Claims 10 or 14. Reis lacks any motivation or suggestion that Alkayali should be modified to meet present Claims 10 or 14. Accordingly, the rejection should be withdrawn.

CONCLUSION

In light of the above amendments and remarks, Applicant earnestly believes that Claims 10-15 are allowable and respectfully requests that they be advanced to allowance. If any additional fees are due in this matter, please charge our deposit account 502323.

Respectfully submitted,

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SPECIFICATION AMENDMENTS

Please cancel the table entitled *Amino acid composition of kolla2* filed as part of the Applicant's amendment dated April 18, 2001.

Please amend the first paragraph of page 2 of the specification as follows:

~~In 1987, the~~ The composition was sold under the name of "Collagen Beauty ProteinTM"
(Smarter Nails & Hair, Inc., Newport Beach, CA). In 1987, "Collagen Beauty Protein TabletsTM"
(Smarter Nails & Hair, Inc., Newport Beach, CA) was sold compressed into 1,000 mg. tablets which
comprised collagen powder and 10 mg. Vitamin C ~~compressed into 1,000 mg. Tablets.~~